

**Wiener lab.**

Especialidades para Laboratorios Clínicos

WIENER LABORATORIOS S.A.I.C. - Riobamba 2944 - 2000 Rosario - Argentina  
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## Section 6 – Summary

### 510(k) Summary

**"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"**

**"The assigned 510(k) number is: K012260"**

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#### Introduction

According to the requirements of 21 CFR 862.1770, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

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#### **6-1 Submitter** **Name, Address,** **Contact**

Wiener Laboratorios S.A.I.C.  
Riobamba 2944  
2000 – Rosario – Argentina  
Tel: 54 341 4329191  
Fax: 54 341 4851986  
Contact person: Viviana Cétola  
Date Prepared: June 23, 2001

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**6-2 Device Name**

Proprietary name: Wiener lab. UREA UV CINETICA AA  
Common name: Urea test system

Classification name: Urease and Glutamic Dehydrogenase, Urea Nitrogen.

Device Class II

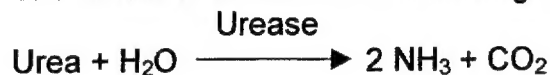
**6-3 Predicate Device**

We claim substantial equivalence to the currently marketed DMA BUN-KINETIC, UREASE PROCEDURE test system (Cat. N° 1770).

**6-4 Device Description**

Kinetic method.

The device is based on the following reaction system:

**6-5 Intended Use**

The UREA UV CINETICA AA test system is intended to be used in the quantitative determination of urea in human serum and plasma. Urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

**6-6 Equivalencies and Differences**

The WIENER UREA UV CINETICA AA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed DMA BUN-KINETIC, UREASE PROCEDURE test system.

The following table illustrates the similarities and differences between the WIENER UREA UV CINETICA AA test system and the currently marketed DMA BUN-KINETIC, UREASE PROCEDURE test system.

	DMA Test System	WIENER LAB. Test System
Intended Use	Quantitative determination of urea in human serum and plasma.	
Test Principle	<p>Kinetic method.</p> <p>The test is based on the following reaction system:</p> $\text{Urea} + \text{H}_2\text{O} \xrightarrow{\text{Urease}} 2 \text{NH}_3 + \text{CO}_2$ $\text{NH}_3 + \text{NADH} + \text{H}^+ + 2\text{-oxoglutarate} \xrightarrow{\text{GIDH}} \text{l-glutamate} + \text{NAD}^+ + \text{H}_2\text{O}$	
Essential Components	2-Oxoglutarate - NADH - Urease - GIDH.	
Working Reagent Stability	14 days	30 days
Instability or deterioration of reagents	<p>Reagent Blank Absorbance &lt; 1.100.</p> <p>Precipitated or hazy standard.</p>	<p>Reagent Blank Absorbance &lt; 1.000.</p>
Sample	Human serum, heparinized plasmas and EDTA plasmas	
Working Temperatures	25 - 37°C	37°C
Wavelength of reading.	340 nm	
Calibration	Single point	
Linearity	<p>100 mg/dl (BUN)</p> <p>214 mg/dl (urea)</p>	<p>140 mg/dl (BUN)</p> <p>300 mg/dl (urea)</p>
Continued on next page		

	<b>DMA Test System</b>	<b>WIENER LAB. Test System</b>
Minimum detection limit	0.4 mg/dl (BUN) 0.9 mg/dl (urea)	1.8 mg/dl (BUN) 3.8 mg/dl (urea)
Expected values	8 – 23 mg/dl (BUN) 17 – 49 mg/dl	4.7 – 23 mg/dl (BUN) 10 - 50 mg/dl (urea)
Intra-assay precision	Normal Serum Control: CV = 4.3%  Abnormal Serum Control: CV = 4.1%	Normal Serum Control: CV = 2.01%  Abnormal Serum Control: CV = 1.19%
Inter-assay precision	Normal Serum Control: CV = 2.9%  Abnormal Serum Control: CV = 6.1%	Normal Serum Control: CV = 2.36%  Abnormal Serum Control: CV = 1.31%

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**6-7 Conclusion** The data above mentioned show substantial equivalency to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Dr. Viviana Cetola  
QA/QC Manager  
Weiner Laboratories S.A.I.C.  
Riobamba 2944  
2000 – Rosairo - Argentina

SEP 19 2001

Re: k012260  
Trade/Device Name: Urea UV Cinetica AA  
Regulation Number: 21 CFR 862.1770  
Regulation Name: Urea nitrogen test system  
Regulatory Class: Class II  
Product Code: CDQ  
Dated: July 4, 2001  
Received: July 18, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

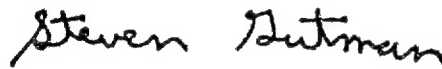
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K 012260

FDA/CDRH/ODE/RL

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510(k) Number (if known): K012260

Device Name: Wiener lab.

Urea UV cinética AA

**Indications For Use:**

The "Wiener lab. Urea UV cinética AA," urea test system is a device intended to measure urea (urea nitrogen) levels in human serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Hevia Alexander for Jean Cooper  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K012260

CH  
II

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)